

Scaling Up the Primary Health Integrated Care Project for Chronic Conditions in Kenya: Study Protocol for an Implementation Research Project

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Study protocol

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Abstract

Background

Amid the rising number of people with NCDs, Kenya has invested in strengthening primary care and in efforts to expand existing service delivery platforms to integrate care for managing chronic disease. One such approach is the AMPATH model, established in 2001 in western Kenya to provide HIV treatment and control services. The model was progressively adapted and developed further to provide care for people with other chronic conditions. Building on this experience, the Primary Health Integrated Care Project for Chronic Conditions (PIC4C) was launched in 2018 to further strengthen primary care services for the prevention and control of hypertension, diabetes, breast and cervical cancer. This study seeks to understand how well PIC4C delivers on its intended aims and to inform and support scale up of the PIC4C model for integrated care for people with selected chronic conditions in Kenya.

Methods

The study is guided by a conceptual framework on implementing, sustaining and spreading innovation in health service delivery. We use a multimethod design combining qualitative and quantitative approaches, involving: (1) in-depth interviews with health workers and decision-makers to explore experiences of delivering PIC4C; (2) a cross-sectional survey of patients newly diagnosed with diabetes or hypertension and in-depth interviews to understand how well PIC4C meets patients' needs; (3) a cohort study with an interrupted time series analysis to evaluate the degree to which PIC4C leads to health benefits such as improved management of hypertension or diabetes; and (4) a cohort study of households to examine the extent to which the national hospital insurance chronic care package provides financial risk protection to people with hypertension or diabetes within PIC4C.

Workshops with decision-makers and other key people at local, county, national and international levels will ensure early and wide dissemination of the findings of the work to allow for the wider scale up of this model of care.

Discussion

Our study will generate new knowledge about the key mechanisms and factors that shape the successful implementation of novel ways of delivering more integrated services to better manage and support people with chronic conditions in low resource settings. It will expand understanding of intended and unintended consequences of integrating NCD management into existing care programmes. This knowledge can be leveraged to inform and improve the design and implementation of similar programmes elsewhere in Kenya and beyond.

Contributions To The Literature

- The rise in NCDs poses an increasing challenge for low- and middle-income countries and many countries are exploring ways to strengthen existing primary health care structures by integrating care for NCDs. Yet, innovative care models are often time-limited and fail to spread beyond localised projects.
- This paper describes a multi-method approach to assess the implementation and potential for scale up of an ambitious innovative model for integrated primary care for chronic conditions in western Kenya. It involves longitudinal data collection to capture changes in experiences among decision-makers, health care workers and patients with chronic conditions over time and the extent to which insurance cover protects people with NCDs, along with secondary analysis of electronic health records to evaluate of the health benefits of the care model.
- Findings will advance understanding of the integrated management of chronic conditions in low resource settings. It will generate new knowledge about the key mechanisms and factors that shape the successful implementation of novel ways of working to deliver more integrated services to better manage and support people with chronic conditions, which will be relevant to settings beyond Kenya.

Background

Like many other countries in sub-Saharan Africa, Kenya faces the double burden of infectious disease and a rising number of people with non-communicable diseases (NCDs). In 2015, NCDs accounted for almost one-third of all deaths and half of hospital admissions; about a quarter of the population had hypertension and 5% had diabetes or impaired fasting glycemia.¹ There are considerable disparities in knowledge about NCDs and their risk factors among the Kenyan population, as well as in access to and use of related services, with the poor remaining especially vulnerable.²⁻⁴ NCDs also have substantial economic consequences in Kenya. For example, households that have at least one member with an NCD are twice as likely to incur catastrophic health expenditure compared to households that do not.⁵ The Kenyan government has sought to enhance financial protection by successively expanding the benefits package of the National Hospital Insurance Fund (NHIF). This expansion is core to the government's approach to achieving universal health coverage, although less than one-fifth of the population is covered.⁶ Recent reforms included the introduction of an expanded benefit scheme ('Supa Cover'⁷), which includes a comprehensive set of services to enhance health care access for people with selected NCDs but levels of uptake are low.⁸

Reorienting health systems towards primary health care is widely seen to be key for the effective prevention and integrated management of people with NCDs and the achievement of universal health coverage more broadly.^{9 10} The Kenyan government has increasingly invested in strengthening primary care,¹¹ but there has remained an emphasis on hospital-based service delivery, which has resulted in long waiting times and reduced quality of care.¹² Lack of systematic screening and early detection, along with lack of capacity at lower levels of care, means that a substantial number of people are diagnosed at an advanced stage of disease, which require specialist input, further increasing the pressures on higher level facilities and their staff. At the same time, there is clear commitment to rebalance service delivery from

curative to preventative and integrated care to manage NCDs more effectively¹¹ and there are examples of novel care models that have extended comprehensive HIV services into the community to serve as a platform for NCD care integration.¹³ One such model is the Academic Model Providing Access to Health Care (AMPATH), which was established in 2001 in western Kenya, initially to provide integrated care for people with HIV.¹⁴

Developed as a partnership between Moi University in Kenya and a consortium of North American academic medical centers, it became one of sub-Saharan Africa's largest HIV treatment and control programmes, and from 2010, the model was progressively developed further to provide care for people with chronic conditions such as hypertension and diabetes, oncology services and mental health care, serving a population of more than 8 million people at over 800 Ministry of Health facilities in 2020.¹⁵ Building on these experiences, the Kenyan Ministry of Health launched, in 2018 and in partnership with AMPATH/Moi, Access Accelerated and the World Bank, a simplified and sustainable integrated model for NCDs, the Primary Health Integrated Care Project for Chronic Conditions (PIC4C) (Box 1).¹⁶ PIC4C aims to strengthen primary care services for the prevention and control of hypertension, diabetes, breast and cervical cancer. It is being piloted in two counties in western Kenya, and implementation is supported by a small-scale evaluation involving a before and after community and facility survey, a limited process evaluation and a costing study.¹⁷ The study proposed here builds on the ongoing evaluation of the PIC4C model, but extends it to understand how well PIC4C delivers on its intended aims and so to inform and support scale up of the PIC4C model for the integrated management of people with hypertension, diabetes and breast and cervical cancers in Kenya.

Box 1. The PIC4C model of care

The PIC4C model aims to identify people with hypertension, diabetes, cervical and/or breast cancer in the community and ensure their timely referral to, treatment and management at the appropriate service level (health centre, dispensary, subcounty or county hospital). Implementation in Busia and Trans Nzoia counties commenced in February 2018.

The PIC4C model includes a range of activities targeting different tiers of the delivery system as well as infrastructural measures. The specific components include (i) training of community health workers to undertake screening, prevention, referral and health education in the community for hypertension, diabetes and cancer; (ii) providing equipment to enable screening, laboratory testing, and treatment of cervical cancer and breast cancer; (iii) strengthening the supply chain system; (iv) health records systems strengthening, building on the AMPATH Medical Record System (AMRS¹⁸); (v) comprehensive training and mentorship of nurses, clinical officers and general practitioners working in primary health care facilities to deliver evidenced based management and referral of patients with these conditions; (vi) linkage to care using structured referral pathways between levels of care and with the voluntary Supa Cover operated by the NHIF for sustainable health financing.

Research objectives

With this study, we seek to:

1. assess the key components of the implementation process of the PIC4C model;
2. understand the experiences of patients to assess whether and how well the PIC4C model meets the needs of those affected by the selected NCDs;
3. assess the health benefits (on hypertension and diabetes) and potential unintended consequences (on HIV viral suppression) of the implementation of the PIC4C pilot; and
4. evaluate the effectiveness of the NHIF chronic care benefit package to provide financial risk protection and understand the degree to which it is responsive to the needs of individuals and influences equity, efficiency, and quality of care.

Conceptual framework

The project is guided by a conceptual framework that draws on our work on implementing, sustaining and spreading innovation in health service delivery.^{19 20} This framework posits that to ensure that service innovation, such as the PIC4C model, is sustained, spread and scaled up, requires leadership and management at different tiers that is supportive of and committed to change; early and widespread stakeholder involvement, including staff and service users; dedicated and ongoing resources, including funding, infrastructure, staff and time; effective communication across and between organizations; adaptation of the innovation to the local context and integration with existing programmes and policies; ongoing monitoring and timely feedback about progress; and evaluation and demonstration of (cost-)effectiveness of the innovation being introduced, including assessment of health benefits. Our project considers all these factors to produce the evidence needed to support the wider spread and potential scale up of the PIC4C model.

Methods/design

We use a multimethod design combining qualitative (sequential in-depth interviews with health workers, decision makers, and patients), and quantitative approaches (patient surveys, a cohort study with an interrupted time series analysis and a cohort study of households with at least one member with hypertension and/or diabetes. Table 1 provides an overview of the key components of the study, outlining the underlying rationale for each study objective as well as approaches to data collection, sampling and proposed analysis.

Table 1
Components of the study

Study objective and sub-objectives	Rationale / hypothesis	Data collection or source	Sampling	Analysis
<p>Understanding the implementation process</p> <ul style="list-style-type: none"> • To assess the quality of leadership and management; levels of stakeholder involvement; adequacy of support mechanisms and resources; ability to adapt the intervention locally; and quality of communication and of monitoring and feedback 	<p>Core to the successful adoption and implementation as well as sustaining of organisational change associated with the introduction of the PIC4C model are the various stakeholders affected by the change, their understanding and acceptance and resultant commitment and buy-in to the proposed changes, in particular by front-line staff.³⁴ Organisational innovations such as the PIC4C are unlikely to succeed long-term if they fail to take into account the diverse patterns of interests, values and power relationships between those involved in the development, implementation and delivery of the new service model.³⁵</p>	<p>In-depth interviews with</p> <ul style="list-style-type: none"> (i) health workers (ii) decision-makers <p>at 3 time points each</p>	<p>Health workers: approximately 40–50 health workers from different levels of service delivery selected from among the 73 health facilities in Busia (n = 20–25) and Trans Nzoia (n = 20–25) counties participating in PIC4C.</p> <p>Decision-makers: approximately 25 decision-makers, including senior health executives and managers of range of health facilities in Busia and Trans Nzoia, purposively sampled to represent different governance levels.</p>	<p>Thematic analysis</p>

Study objective and sub-objectives	Rationale / hypothesis	Data collection or source	Sampling	Analysis
<p>Understanding patient experience</p> <ul style="list-style-type: none"> • To assess whether and how well the PIC4C model meets the needs of those affected by diabetes and hypertension 	<p>There are widely documented challenges of retaining people positively screened for a given NCD in care and adhering to treatment in Kenya.³⁶ ³⁷ The reasons for this include financial difficulties³⁸ with more recent evidence pointing to the role of ‘treatment burden’ for adherence to treatment and quality of life.³⁹ Assessing this burden provides a useful lens to explore the degree to which the PIC4C model supports people with NCDs in managing their condition and is able to identify and target subgroups of patients at risk of poor outcomes because of lack of capacity and resources to engage in self-care and treatment.</p>	<p>(i) Patient survey of experiences with treatment and self-management (PETS)</p> <p>(ii) In-depth interviews with patients at 3 time points</p>	<p>PETS: random sample that is representative of people with hypertension and/or diabetes in terms of age, gender and broad socio-economic status; we seek to arrive at a total sample of around n = 300. This sample size was used by the developers of the PETS survey instrument to test its validity.²¹</p> <p>Patient interviews: sampled from patients who have responded to the PETS, aiming to interview 15–20 patients in each county (total sample: 30–40 patients), with attention to recruiting those who may face challenges in accessing services as identified from PETS.</p>	<p>PETS: Descriptive statistics</p> <p>Patient interviews: Thematic analysis</p>

Study objective and sub-objectives	Rationale / hypothesis	Data collection or source	Sampling	Analysis
<p>Evaluation of health benefits</p> <ul style="list-style-type: none"> • To identify individual-level factors associated with levels of hypertension, diabetes and HIV viral suppression • To identify facility-level factors associated with levels of hypertension, diabetes and HIV viral suppression • To evaluate temporal trends and the impact of scaling up the PIC4C model on health benefits and potential unintended consequences 	<p>The introduction of the PIC4C model will lead to a significant improvement in the management of hypertension and diabetes without adversely affecting HIV management (as measured using HIV viral suppression levels). Primary outcomes, treated as continuous variables, will differ according to diagnosis: systolic blood pressure (hypertension), fasting glucose and Hba1c (diabetes). In patients with more than one diagnosis all relevant outcomes will be considered. Secondary outcomes will include overall cardiovascular risk (as estimated by the WHO Risk Score⁴⁰), treated as continuous variable, hypertension control (< 140/90), diabetes control (fasting glucose: FBS < 8.0mmol/L, RBS < 10mmol/L), and HIV viral suppression (< 1000 copies/ml) treated as binary variables. We further seek to assess a range of process outcomes, such as guideline adherence; treatment initiation, adherence and retention; referral; lifestyle recommendations; number of diagnostic tests performed; and, at facility level; drug availability.</p>	<p>Cohort study of patients with hypertension, diabetes and/or HIV/AIDS</p>	<p>Estimated sample size of 8,000 patients with hypertension, 1,000 with diabetes, and 1,000 with diabetes and hypertension required to detect a reasonable and relevant impact of the PIC4C model for all outcomes (90% power) based on the assumptions: systolic blood pressure change of 5 mm hg (SD 15) ICC 0.05, HbA1c change 0.37% (SD 1.1%) ICC 0.04.⁴¹</p>	<p>Sub-objectives 1 & 2: Descriptive statistics</p> <p>Sub-objective 3:</p> <p>Patient visit-level analysis: Directed Acyclic Graphs (DAGs) informed linear mixed-effects models for continuous and generalized mixed-effect models for binary outcomes</p> <p>Facility-level analysis:</p> <p>Interrupted time-series analysis</p>

Study objective and sub-objectives	Rationale / hypothesis	Data collection or source	Sampling	Analysis
<p>Assessment of effectiveness of NHIF chronic care benefit package</p> <ul style="list-style-type: none"> • To measure the effectiveness of the NHIF national scheme benefit package to provide financial risk protection to individuals with chronic diseases • To examine the extent to which the NHIF national scheme benefit package is responsive to the needs of individuals with hypertension, diabetes, cervical and breast cancer • To examine how the provider incentives generated by provider payment arrangements of the NHIF national scheme benefit package influence equity, efficiency, and quality of care 	<p>Enrolment in a health insurance scheme does not always translate into expanded access to health care and financial risk protection.⁴² Also, purchasing arrangements, specifically the relationship between purchasers (such as the NHIF) and health care providers as well as provider payment mechanisms can influence provider behaviour in a way that shapes the equity, efficiency, and quality of service provision.⁴³ Understanding these aspects of the NHIF national scheme benefit package will provide evidence about its scalability as a financial risk protection mechanism for households with members with a chronic disease. It will further inform design refinements to help improve scalability of the programme.</p>	<p>(i) Cohort study of households with at least one member with hypertension, diabetes or both</p> <p>(ii) In-depth interviews (IDIs) with decision-makers, facility managers and health care workers</p> <p>(iii) Focus group discussions (FGDFGDs) with patients with diabetes/hypertension and household heads</p>	<p>(i) Target sample of n = 960 individuals, with n = 480 enrolled in NHIF and n = 480 not enrolled in NHIF; each subsample to include n = 160 individuals with hypertension, n = 160 with diabetes and n = 160 with both conditions. Estimates based on detection of a 15-percentage point difference in the proportion of catastrophic health expenditure (40% in the control group), a design effect of 1.2, and a two-sided alpha level of 0.05 (80% power and estimated 60% attrition); sample stratified by county and chronic condition.</p> <p>(ii) Target sample of 54 IDIs across national, and county and health facility levels in Busia</p>	<p>(i) Descriptive statistics; Generalized Estimating Equations (GEE) with OOP as dependent and NHIF enrolment as independent variables; estimation of concentration curves and indices</p> <p>(ii) Thematic analysis</p>

Study objective and sub-objectives	Rationale / hypothesis	Data collection or source	Sampling	Analysis
			and Trans Nzoia. (iii) 4 FGDs (each with approximately 10–12 participants), 2 each in Busia and Trans Nzoia counties, covering rural and urban areas.	

Note: ICC – Intraclass correlation coefficient; NCD – non-communicable disease; NIHF – National Hospital Insurance Fund; PETS – Patient Experience with Treatment and Self-Management; SD – standard deviation

Settings and site selection

The public health care delivery system in Kenya is organized into four tiers and six levels: (i) community health services (level 1) include all community-based activities that are guided by the Ministry of Health (MOH); (ii) primary care includes services provided by public dispensaries (level 2 facilities) and health centres (level 3 facilities); (iii) county referral services include first referral subcounty hospitals (level 4 facilities) and second referral county hospitals (level 5) that are managed by the county; the 4th tier includes national referral services (level 6), namely tertiary referral hospitals.

The PIC4C model is implemented across 73 level 2–5 facilities in Busia and Trans Nzoia counties (Appendix Table A.1). Table 2 provides an overview of the range of facilities participating in the pilot which will serve as sampling frame for the present study.

Table 2
Number and type of facilities in Busia and Trans Nzoia counties participating in PIC4C

	Busia (7 subcounties)	Trans Nzoia (5 subcounties)
County hospital (Level 5)	1	1
Subcounty hospital (Level 4)	7	5
Health centre (Level 3)	10	13
Dispensary (Level 2)	22	13
Other	-	1 (private non-profit medical centre)
Total	40	33

Data types and collection

The following data types will be collected: in-depth interviews with patients, health workers and decision-makers; focus group discussions with patients; a patient survey of experiences with treatment and self-management; patient data extracted from the AMPATH Medical Records System (AMRS), complemented by data extracted from health facility registers.

We will conduct two distinct series of **in-depth interviews with health workers and decision-makers**. The first series relates to *Objective 1* of the study. This involves interviews with health workers (physicians, clinical officers, nurses, laboratory staff, community health workers and Community Health Volunteers (CHVs), who are working at different levels of service delivery in Busia and Trans Nzoia counties and with decision-makers at the different tiers of the health system, including those involved in the governance and administration of Busia and Trans Nzoia's health systems (from county executive committee secretary to managers of individual health facilities) and county and national level decision-makers. Sampling will be carried out purposively. Interviews will be semi-structured, following a topic guide that is informed by existing work on implementation. We will develop topic guides that are specific to the target group (health worker; facility manager; decision-maker) and cover questions around the quality of leadership and management; perceptions of and attitudes to the PIC4C model; levels of stakeholder involvement; adequacy of support mechanisms and resources; ability to adapt the intervention locally; quality of communication and of monitoring and feedback; and perceived challenges in the day-to-day delivery of the new service model.

The second series of in-depth interviews relates to *Objective 4*. For this, we will also carry out interviews with decision-makers at the different tiers of the health system but focus our enquiry specifically on those with a role in financing, including representatives of the NHIF at national and county levels, and their counterparts at the Ministry of Health and county health management, as well as managers of public and private health facilities. Interviews will be semi-structured, using a topic guide seeking to explore questions around the appropriateness of the NHIF benefit package to meet the needs of patients with

chronic conditions, as well as perceived adequacy of provider payment to deliver the expected services in a way that achieves the goals of equity, efficiency, and quality.

In-depth interviews with patients. To address *Objective 2*, we will carry out interviews with patients newly diagnosed with diabetes and/or hypertension from different socio-demographic backgrounds, their location in the patient journey (newly diagnosed, commenced treatment, drop out, etc.) as well as geographic location (distance to health facilities), among other factors as identified from the patient survey (see below) to provide insight into likely care gaps and fragmentation from the perspective of those receiving care. Interviews with patients will follow a semi-structured interview guide, informed by the literature on treatment and self-management burden, while also exploring people's experiences of the health service, including how the new/expanded service delivery model is making a difference to their experience. Interviews will seek to capture the experience of patients along the care pathway, with a focus on transition points between care levels; their level of involvement in treatment decisions; perceived quality of communication with the health worker (physician, clinical officer, nurse, CHV); and issues faced in terms of access and adherences to treatment.

All interviews will be conducted in English or Swahili, with topic guides translated (forward/backtranslation) and piloted with a small sample of the respective interview group. *Objective 1 and 2* interviews will be conducted at three points in time over the duration of the project; *Objective 4* interviews will be conducted at one point in time only. All interviews will be carried out face-to-face by researchers trained in qualitative methods in a location most convenient for the interview participant. Patient interviews will be carried out at a health facility closest to invited participants' home. Participants will be reimbursed to cover the cost of travel and will also be offered refreshments. We expect interviews to last between 45–60 minutes for health workers and decision-makers and up to 90 minutes for patients.

Objective 4 further foresees **focus groups discussions (FGDs) with patients**. These will be conducted with households that are enrolled in NHIF and that have at least one member with hypertension and/or diabetes. FGDs will include affected individuals and their household head and seek to ensure a balance of gender representation. FGDs will be guided by a topic guide, exploring participants' experiences around accessing care, and their perceptions about the extent to which the NHIF national scheme meets their needs as patients with chronic disease. FGDs will be facilitated by researchers trained in qualitative methods.

Patient survey of experiences with treatment and self-management. As part of *Objective 2*, we will conduct a survey of patients who screened positively for hypertension and/or diabetes using an adapted version of the 'Patient Experience with Treatment and Self-Management' (PETS)²¹ tool to understand their perceived treatment and self-management burden. The instrument has been developed and validated in a US setting, and has recently been translated and adapted to the Norwegian context.²² We will test whether the questions in the current version of PETS are appropriate in the Kenyan context and add questions about the respondents' socio-demographic background and health status. We will

translate and back-translate the instrument into Swahili and test with 6–8 patients. We will use computer-assisted personal interviewing with trained research assistants and the REDCap platform, a secure web application for building and managing online surveys and databases, which is already being used for data collection in the ongoing PIC4C evaluation. The survey will include an additional question asking participating respondents whether they would be happy to be contacted subsequently for an in-depth interview to further explore their experiences with treatment and self-management of their condition/s.

Cohort study of patients with hypertension, diabetes and/or HIV/AIDS. The study population includes all adult (> 18 years) patients with a diagnosis of hypertension, diabetes, and/or HIV/AIDS. We will use the existing AMRS, in which each patient has been assigned a unique universal identifier and which is used in the management of their care across all levels. In addition to the primary outcomes (systolic blood pressure, and fasting glucose or Hba1c-depending on availability) we will collect data on HIV viral suppression (< 1000 copies/ml), process outcomes, and potential confounders at the facility and individual level. Based on data from the current AMRS we estimate that approximately 8,000 patients with hypertension, 1,000 with diabetes, and 1,000 with diabetes and hypertension will fulfil the inclusion criteria and will be included in the interrupted time-series analysis.

Cohort study of households with at least one member with hypertension or diabetes. The study population for this component includes households with at least one adult (18 years and older) member with hypertension and/or diabetes residing in Busia and Trans Nzoia counties and considers those enrolled with NHIF as exposed group and those without insurance coverage as control). Eligible households will principally be identified from the AMPATH/Moi university screening database that has been developed as part of the PIC4C programme. However, preliminary exploration of the screening database revealed that the number of people with known NHIF registration status will be insufficient to achieve our desired sample size (see Table 1). We will therefore complement this source with (i) the wider AMRS database and/or (ii) health facility registers to identify households that meet our inclusion criteria. Data collection involves a structured questionnaire which will be administered at enrolment into the study with follow-up at months 3, 6, 9 and 12, supplemented by patient diaries. The questionnaire will be administered by research assistants, using computer-assisted personal interviewing based on the REDCap platform and/or the CommCare application. Respondents to be interviewed will include the head of the household and the household member with hypertension and/or diabetes, collecting information on health care-seeking events, general household expenditure, and health care expenditure, alongside a series of household characteristics (household members' age, sex, educational attainment, marital status, occupation, religion, socioeconomic status proxies (asset ownership and dwelling characteristics), residence, number of household members with a chronic condition, and health insurance coverage other than NHIF). The responding household member with hypertension/diabetes will also be invited to keep a diary recording health-seeking events and health care expenditures. The diary will be checked by data collectors to validate survey responses.

Data analysis

In-depth interviews and focus group discussions. Interviews and focus group discussions will be recorded, with participants' permission, and stored on the secure Moi network. They will be transcribed and translated into English. Interview transcripts will be delinked from any personal information and allocated a unique identifier comprising county code, date, and anonymised participant identifier to ensure confidentiality. Interview transcripts will be analysed, principally following a thematic approach.²³

²⁴ This includes familiarisation with the data through reading and rereading transcripts and organising data by means of coding and re-coding of data through a series of reflexive steps. Codes will be initially generated from the interview guide and literature, with additional codes added as data are analysed. We will use NVivo Software to assist with data management. Transcripts will be analysed for each participant group and round and comparisons drawn between the first, second and third round data to explore changes as a result of PIC4C implementation.

Patient survey of experiences with treatment and self-management. Survey data will be imported into Stata and analysed using simple descriptive statistics (continuous data will be presented as means and standard deviations, and discrete data presented as frequencies and percentages) as the main aim is to understand the prevalence of the treatment and self-management burden among a group of newly diagnosed people and to understand its distribution across a range of socio-demographic and -economic characteristics. This will then help inform recruitment for in-depth interviews with a smaller group of patients to gain further insight into the underlying issues that will help explain the challenges experienced and so inform the further development and scale up of the PIC4C model.

Cohort study of patients with hypertension, diabetes and/or HIV/AIDS. Analyses will use individual (patient visit) level data and health services (facility) monthly aggregated level data. We will first conduct descriptive analysis using patient, patient visit and facility level data to identify individual-level and facility-level factors associated with levels of hypertension, diabetes and HIV viral suppression. We will generate a panel time series dataset and describe the number of visits, of patients and reported outcomes within each facility at each month. We will explore possible changes in the underlying population composition over time and describe the proportion of patients achieving diabetes and hypertension control and be virally suppressed per month. We further seek to examine patient visit patterns, including the distribution of visits per patient and facility and to identify patients with at least one visit before and after the implementation of PIC4C so as to examine, in sensitivity analyses, the impact of the new model of care on patient outcomes. Descriptive analyses will take account of potential confounders and effect modifiers at patient and facility level informed by causal inference framework using directed acyclic graphs (DAGs).²⁵

Facility level analyses will use interrupted time series analysis using monthly facility level aggregated data to examine the impact of the PIC4C model on all outcomes. The main impact model will assume a stable level change after the PIC4C implementation which has been achieved progressively within the implementation period (June 2019 to November 2019). The time periods before and after the model implementation will constitute the two segments of our regression models considering 24 monthly time points before and 24 monthly time points after. Analyses will consider an implementation period of 6

months in which the intervention is being rolled out. We will assess autocorrelation by examining the plot of residuals and the partial autocorrelation function and, perform Durbin-Watson test statistics to evaluate serial autocorrelation. Where there is evidence of auto-correlation we will adjust using autoregressive integrated moving average. The Augmented Dickey-Fuller test statistic will be used to evaluate the presence of unit roots. If there is evidence of auto-correlation we will adjust using autoregressive integrated moving average. Seasonality will be examined and accounted for in all models.

Cohort study of households with at least one member with hypertension or diabetes. Analyses will include, first, a descriptive component, summarising the findings by computing annualised means and medians of health expenditure overall and by key sample characteristics such as chronic condition. The primary outcome will be level of out-of-pocket (OOP) health expenditure, which we will compute as the proportion of total per capita household consumption expenditure. We will employ Generalized Estimating Equations (GEE) to assess whether the level of OOP health expenditure is significantly different between households enrolled in the NHIF and those that are not, using level of OOP expenditure as dependent variable and NHIF enrolment status as main independent variable. In the GEE model, we will account for clustering at health facility level and apply the mixed effect of multi-level covariates. To account for potential confounding, we will conduct a post-hoc matching of households on characteristics that may drive health care expenditure, such as the number of people in the households, gender, chronic condition, county of residence, socio economic status and number of older people living in the household. We will use the coarsened exact matching method (CEM), which seeks to control for the potential confounding influence of 'pre-treatment' covariates on the outcome of interest, by matching 'treatment' cases with 'non-treatment' cases that are approximately similar to them with regard to those covariates. In our case, 'treatment' cases are households enrolled in NHIF and 'non-treatment' controls are households that are not. The magnitude of the insurance effect will be measured by the adjusted values of coefficients of NHIF enrolment and significant results will be established at $p < 0.05$. The coefficients of the covariates will be converted into risk ratio (RR) or incidence rate ratios (IRR), as appropriate, with 95% confidence intervals reported. To explore inequality in financial risk protection, we will develop concentration curves and compute concentration indices of the level of OOP expenditure by categorising the households in the sample into 5 socio-economic quintiles, (5 richest, 1 poorest) using the annual total household consumption expenditures as the measure for household wealth. All statistical analyses will be carried out using Stata version 14.

Ethical approval

Ethical approval has been granted for all elements of this study. Informed consent will be obtained from all participants in this study through their signatures on an informed consent form, in which participants confirm that they have read and understood the project information sheet. Additionally, at the beginning of each interview or the patient/household survey, the interviewer/survey administrator will seek verbal consent that participants have read the participant information sheet, that they are still willing to be interviewed/complete the survey and, in case of the interview, that they agree that it will be audio recorded and transcribed. All material will be made available in English or Swahili. In case of participants unable to

read the information sheet and consent form, these will be read out to them in their native language (Swahili or other) and verbal consent will be requested. Where participants are unable to sign with their own name, they will be invited to give informed consent using their fingerprint, with co-signature required of an impartial witness who is over 18 years of age and capable of understanding the informed consent; where a suitable witness cannot be identified, the participant will not be interviewed.

All electronic data will be maintained in a secure password-protected environment and any hard copies of interview transcripts and consent forms will be kept in a locked cabinet. Once data have been processed and databases created, they will be encrypted, password-protected and saved in the Moi University secured network.

Knowledge translation

We will develop a formal communication and impact strategy based on the ESRC toolkit²⁶ and with the support of the communication departments of participating institutions. This will include impact objectives, mapping of key beneficiaries and audiences, an activity plan, targeted messages and activities for different stakeholders/audiences, and monitoring and evaluation of impact indicators. We have strong established relationships with some of the key knowledge users (MoH, the World Bank and decision makers at county levels), which contributed to the key research questions and proposed methods presented here, are part of a study advisory committee and will be key to achieve the expected impact of the project. We will build on this through early dissemination of emerging insights to inform the possible scale up of the PIC4C model across Kenya and other countries participating in the Access Accelerated/World Bank initiative. We will do so by holding two formal stakeholder workshops throughout the lifetime of the project and a closing policy dialogue towards the end. The workshops will include key stakeholders that are directly and indirectly involved in the PIC4C model development and implementation as well as national and county level political and health system leaders, academic and AMPATH leaders, senior level service providers, civil society, and stakeholders from the other WB/AAI participating countries. Stakeholder workshops aim to (i) communicate emergent insights from the work; (ii) actively engage stakeholder and use their knowledge and experience to reflect on emergent findings; and (iii) work with stakeholders to begin formulating draft recommendations for a regional and/or national scale up strategy. They will also provide opportunity for adapting proposed work to ensure that the research meets the information needs of key stakeholders involved in the organisation and governance of the Kenyan health system at county and national levels. A final policy dialogue will be aimed at high-level national and international policy-makers to disseminate the findings of the research to a broader policy audience with a view to inform implementation and scale up of integrated primary care approaches beyond Kenya.

Discussion

The burden of disease has changed globally, with a rise in NCDs posing an increasing challenge for low- and middle-income countries. However, health systems continue to emphasise specialist services, with a

focus on an acute, episodic model of care which is not well suited to meet the requirements of people with multiple care needs associated with NCDs and services are not well integrated across the different care levels. Strengthening of primary health care is widely accepted to be core to the development of more integrated health services, and a foundation for a sustainable health system.^{27 28} Many countries are exploring ways to strengthen existing primary health care structures by integrating care for NCDs, through, for example, into routine HIV services in many parts of sub-Saharan Africa.²⁹ However, while there are many promising examples of innovative care models, these are often implemented as time-limited pilots, ending when project funding ends, or, where pilots have sustained, they tend to not spread beyond localised projects,³⁰ despite increasing evidence on the key factors facilitating scale-up of innovations in low resource settings.^{31 32}

Our study has many strengths. First, it evaluates an ambitious innovative model, triangulating different methodological approaches and involving all key stakeholders from the beginning and throughout all study phases. Second, it will make a unique contribution to the emerging evidence and theory development on complexity around treatment and self-management burden among people with NCDs, which is a comparatively new field, in particular in low resource settings.³³ Third, by adopting a longitudinal approach, we will be able to capture changes in experiences among decision-makers, health care workers and patients with NCDs over time. In addition, the collection of household health expenditure data over the course of an entire year the study will address be able to address seasonal biases that are typical for one-off expenditure surveys conducted elsewhere. A final strength is the use of secondary analysis of electronic health records (AMRS) and cutting-edge statistical approaches such as interrupted time series analysis informed by causal frameworks.

Our study is not without limitations, however. A drawback is that the PIC4C model of care is implemented in two counties in western Kenya only and it will be difficult to derive generalisable findings for all of Kenya. Our main interest is in the experiences of decision-makers, health care workers and patients of the new model of care and how these change over time to help inform a possible roll-out of the care model to other parts of Kenya. We use in-depth interviews to understand nuances in these experiences rather than opting for larger-scale surveys, which may be more representative of the local population, but which would be limited regarding the level of insight that we are seeking. At the same time, we employ a survey to assess the effectiveness of the NHIF chronic care benefit package; this will likely provide us with a representative view of the degree to which the benefit package provides financial risk protection to individuals with chronic diseases. However, the survey will have to rely, to considerable extent, on self-reported expenditure, which is always vulnerable to recall bias. We will seek to minimise potential bias by also including diaries alongside the survey instrument. Finally, while this study is in the fortunate position to draw on the well-developed AMPATH Medical Record System, the use of electronic health records for research purposes can be fraught in that variables that are key for answering the research question may be missing and/or, for variables for which data is collected, there might be missing information. Notwithstanding these challenges, to best of our knowledge, our study, will still be the first to use a large

dataset based on electronic health records for evaluating an innovative model for the management of NCDs in SSA.

Overall, using a pragmatic, comprehensive and innovative methodological approach, our study will advance understanding of the integrated management of chronic conditions in low resource settings. It will generate new knowledge about the key mechanisms and factors that shape the successful implementation of novel ways of working to deliver more integrated services to better manage and support people with chronic conditions, which will be relevant to settings beyond Kenya. It will provide important new insights into the requirements for scaling up a novel approach to managing NCDs in primary health care from the perspective of those organising, delivering, and receiving the enhanced services while also expanding our understanding of the unintended consequences of integrating NCD management into the primary care platform on existing care programmes. This knowledge can then be leveraged to inform and improve the design and implementation of similar programmes elsewhere in Kenya and beyond.

Declarations

Ethics approval

Approved by the Institutional Research and Ethics Committee from Moi University on 2 April 2020 and from the London School of Hygiene & Tropical Medicine on 14 February 2020. In line with the ethical approval, informed consent will be obtained from all study participants.

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

PP, JK, EN, VN, AM, AG, KH, AE and EB conceptualised the study and obtained funding. HK, TP, RO and VW contributed to the methodological development and study design. RM will support data management and participant recruitment. HK, RO, and VW will lead on all planned data collection; all authors will support the data analysis. EN drafted the manuscript. All authors read and approved the final manuscript.

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References

1. Ministry of Health Kenya. STEPwise survey for non communicable diseases risk factors 2015 report Nairobi: Kenya Ministry of Health, 2015.
2. Subramanian S, Gakunga R, Kibachio J, et al. Cost and affordability of non-communicable disease screening, diagnosis and treatment in Kenya: Patient payments in the private and public sectors. *PLOS ONE* 2018;13(1):e0190113.
3. Oyando R, Njoroge M, Nguhiu P, et al. Patient costs of diabetes mellitus care in public health care facilities in Kenya. *Int J Health Plan Manage* 2020;35(1):290-308.
4. Oyando R, Njoroge M, Nguhiu P, et al. Patient costs of hypertension care in public health care facilities in Kenya. *Int J Health Plan Manage* 2019;34(2):e1166-e1178.
5. Barasa E, Maina T, Ravishankar N. Assessing the impoverishing effects, and factors associated with the incidence of catastrophic health care payments in Kenya. *Int J Equity Health* 2017;16:31.
6. Barasa E, Rogo K, Mwaura J, et al. Kenya National Hospital Insurance Fund Reforms: Implications and Lessons for Universal Health Coverage. *Health Syst Reform* 2018;4:346-61.
7. National Hospital Insurance Fund. NHIF SUPA Cover Products. 2000. <http://www.nhif.or.ke/healthinsurance/supacoverServices> (last accessed 19 November 2020).
8. Mbau R, Kabia E, Honda A, et al. Examining purchasing reforms towards universal health coverage by the National Hospital Insurance Fund in Kenya *Int J Equity Health* 2020;19:19.
9. Bitton A, Fifield J, Ratcliffe H, et al. Primary healthcare system performance in low-income and middle-income countries: a scoping review of the evidence from 2010 to 2017. *BMJ Glob Health* 2019;4:e001551.
10. Hone T, Macinko J, Millett C. Revisiting Alma-Ata: what is the role of primary health care in achieving the Sustainable Development Goals? *Lancet* 2018;392:1461–72.
11. Ministry of Health Kenya. Kenya primary health care strategic framework 2019-2024. Nairobi: Ministry of Health, 2019.

12. The World Bank. Laying the foundation for a robust health care system in Kenya. Kenya public expenditure review. Vol. II. Nairobi: The World Bank, 2014.
13. Njuguna B, Vorkoper S, Patel P, et al. Models of integration of HIV and noncommunicable disease care in sub-Saharan Africa: lessons learned and evidence gaps. *AIDS* 2018;32:S33–S42. .
14. Einterz R, Kimaiyo S, Mengech H, et al. Responding to the HIV pandemic: the power of an academic medical partnership. *Acad Med* 2007;82:812-8.
15. AMPATH. Our story. 2020. URL: <https://www.ampathkenya.org/history> (last accessed 19 November 2020).
16. Schneidman M, Seiter A. Allies in a battle against non-communicable diseases in Kenya. World Bank Blogs. 2020. <https://blogs.worldbank.org/health/allies-battle-against-non-communicable-diseases-kenya> (last accessed 19 November 2020).
17. Andale T, Kirui N, Naanyu V, et al. Primary health care integration for four chronic diseases in Western Kenya: The PIC4C baseline study protocol. *J Kenya Association of Physicians* 2020.
18. Tierney W, Rotich J, Hannan T, et al. The AMPATH medical record system: creating, implementing, and sustaining an electronic medical record system to support HIV/AIDS care in western Kenya. *Stud Health Technol Inform* 2007;129:372-6.
19. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004;82:581-629.
20. Nolte E, Anell A. The person at the centre? The role of self-management and self-management support. In: Nolte E, Merkur S, Anell A, eds. *Achieving person-centred health systems: evidence, strategies and challenges*. Cambridge Cambridge University Press, 2020:317-345.
21. Eton D, Yost K, Lai J, et al. Development and validation of the Patient Experience with Treatment and Self-management (PETS): a patient-reported measure of treatment burden. *Qual Life Res* 2017;26:489-503.
22. Husebø A, Morken I, Eriksen K, et al. The patient experience with treatment and self-management (PETS) questionnaire: translation and cultural adaptation of the Norwegian version. *BMC Med Res Methodol* 2018;18:147.
23. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77-101.
24. Patton M. *Qualitative research and evaluation methods*. London: SAGE Publications 2002.
25. Greenland S, Pearl J, Robins J. Causal diagrams for epidemiologic research. *Epidemiol* 1999;10:37-48.
26. Economic and Social Research Council. Impact toolkit. 2020. <https://esrc.ukri.org/research/impact-toolkit/> (last accessed 19 November 2020).
27. Global Conference on Primary Health Care. Declaration of Astana. 2018. <https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf> (last accessed 19 November 2020).

28. Petticrew L, De Maesener J, Anderson M, et al. Primary health care and the Sustainable Development Goals. *Lancet* 2015;386:2119-21.
29. Kintu A SD, Okello S, Mutungi G, Guwatudde D, Menzies NA, Danaei G, Verguet S. . Integrating care for non-communicable diseases into routine HIV services: key considerations for policy design in sub-Saharan Africa. *J Int AIDS Soc* 2020;23
30. Spicer N, Bhattacharya D, Dimka R, et al. 'Scaling-up is a craft not a science': Catalysing scale-up of health innovations in Ethiopia, India and Nigeria. *Soc Sci Med* 2014;121:30-8.
31. Spicer N, Hamza Y, Berhanu D, et al. 'The development sector is a graveyard of pilot projects!' Six critical actions for externally funded implementers to foster scale-up of maternal and newborn health innovations in low and middle-income countries. *Global Health* 2018;27
32. Bulthuis S, Kok M, Raven J, et al. Factors influencing the scale-up of public health interventions in low- and middle-income countries: a qualitative systematic literature review. *Health Policy Plan* 2020;35:219-34.
33. Sav A, Salehi A, Mair F, et al. Measuring the burden of treatment for chronic disease: implications of a scoping review of the literature. *BMC Med Res Methodol* 2017;12:140.
34. Nolte E. How do we ensure that innovation in health service delivery and organization is implemented, sustained and spread? Copenhagen: World Health Organization 2018 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies), 2018.
35. Langley A, Denis J-L. Beyond evidence: the micropolitics of improvement. *BMJ Quality & Safety* 2011;20(Suppl. 1):i43-6.
36. Naanyu V, Vedanthan R, Kamano J, et al. Barriers Influencing Linkage to Hypertension Care in Kenya: Qualitative Analysis from the LARK Hypertension Study. *J Gen Intern Med* 2016;31:304-14.
37. Rachlis B, Naanyu V, Wachira J, et al. Identifying common barriers and facilitators to linkage and retention in chronic disease care in western Kenya. *BMC Public Health* 2016;16:741.
38. Subramanian S, Gakunga R, Kibachio J, et al. Cost and affordability of non-communicable disease screening, diagnosis and treatment in Kenya: Patient payments in the private and public sectors *PLoS One* 2018;13:e0190113.
39. Matima R, Murphy K, Levitt N, et al. A qualitative study on the experiences and perspectives of public sector patients in Cape Town in managing the workload of demands of HIV and type 2 diabetes multimorbidity. *PLoS One* 2018;13:e0194191.
40. WHO CVD Risk Chart Working Group. World Health Organization cardiovascular disease risk charts: revised models to estimate risk in 21 global regions. *Lancet Glob Health* 2019;7:e1332-45.
41. Jha D, Gupta P, Ajay V, et al. Protocol for the mWellcare trial: a multicentre, cluster randomised, 12-month, controlled trial to compare the effectiveness of mWellcare, an mHealth system for an integrated management of patients with hypertension and diabetes, versus enhanced usual care in India. *BMJ Open* 2017;7:e014851.

42. Xu K, Evans D, Carrin G, et al. Protecting households from catastrophic health spending. *Health Aff* 2007;26:972–83.
43. Barasa E, Hanson K, Kabia E, et al. Multiple funding flows to health providers: A conceptual framework to assess and options to align them. Working Paper. Nairobi: KEMRI, 2020.
44. Anon. Primary Health Integrated Care Project for Chronic Diseases; (PIC4C). Project protocol. Eldoret: MOI, 2018.
45. Kenya National Bureau of Statistics. 2019 Kenya Population and Housing Census. <https://kenya.opendataforafrica.org/msdpnbc/2019-kenya-population-and-housing-census-population-by-county-and-sub-county?county=1003270-busia> (last accessed 20 March 2021).

Appendix

Table A.1 Key features of Busia and Trans Nzoia counties (2018)

Characteristics	Busia county	Trans Nzoia county
Population	893,681*	990,341*
% population aged 15+ years	52%	53%
% females	52%	51%
Live expectancy at birth	47 years	60.5 years
Poverty level	64%	50%
Estimated hypertension prevalence	22%	27%
Estimated diabetes prevalence	1.5%	2%
NHIF coverage	31%	20%
Number of public health facilities	184 community units served by 47 dispensaries, 12 health centers, 5 sub-county and 1 county hospital	198 community units served by 38 dispensaries, 8 health centers, 6 sub-county health facilities and 1 county hospital
Number of patients with selected NCDs serviced in AMPATH sites	6060 patients with hypertension, 1113 with diabetes and 200 with cervical cancer.	4,375 patients with hypertension, and 2,089 with diabetes.

Sources: PIC4C project protocol⁴⁴; * 2019⁴⁵